

105TH CONGRESS
1ST SESSION

S. 87

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

IN THE SENATE OF THE UNITED STATES

JANUARY 21, 1997

Ms. SNOWE (for herself and Mrs. FEINSTEIN) introduced the following bill;
which was read twice and referred to the Committee on Labor and
Human Resources

A BILL

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. INFORMATION PROGRAM ON DRUGS FOR SERI-**
4 **OUS OR LIFE-THREATENING DISEASES.**

5 Section 402 of the Public Health Service Act (42
6 U.S.C. 282) is amended—

7 (1) by redesignating subsections (j) and (k) as
8 subsections (k) and (l), respectively; and

1 (2) by inserting after subsection (i), the follow-
2 ing new subsection:

3 “(j)(1) The Secretary, acting through the Director of
4 the National Institutes of Health, shall establish, main-
5 tain, and operate a program with respect to information
6 on research, treatment, detection, and prevention activities
7 relating to serious or life-threatening diseases and condi-
8 tions. The program shall, with respect to the agencies of
9 the Department of Health and Human Services, be inte-
10 grated and coordinated, and, to the extent practicable, co-
11 ordinated with other data banks containing similar infor-
12 mation.

13 “(2)(A) After consultation with the Commissioner of
14 Food and Drugs, the directors of the appropriate agencies
15 of the National Institutes of Health (including the Na-
16 tional Library of Medicine), and the Director of the Cen-
17 ters for Disease Control and Prevention, the Secretary
18 shall, in carrying out paragraph (1), establish a data bank
19 of information on clinical trials and treatments (including
20 drugs, biologicals, devices, and other therapies) with re-
21 spect to serious or life-threatening diseases and conditions.

22 “(B) In carrying out subparagraph (A), the Secretary
23 shall collect, catalog, store and disseminate the informa-
24 tion described in such subparagraph. The Secretary shall
25 disseminate such information through information sys-

1 tems, which shall include toll-free telephone communica-
2 tions, available to individuals with serious or life-threaten-
3 ing diseases and conditions, to other members of the pub-
4 lic, to health care providers, and to researchers.

5 “(3) The Data Bank shall include the following:

6 “(A) A registry of clinical trials (whether feder-
7 ally or privately funded) of experimental treatments
8 (including drugs, biologicals, devices, and other
9 therapies) for serious or life-threatening diseases
10 and conditions under regulations promulgated pur-
11 suant to sections 505 and 520 of the Federal Food,
12 Drug, and Cosmetic Act that provides a description
13 of the purpose of each experimental drug protocol,
14 either with the consent of the protocol sponsor, or
15 when a trial to test efficacy begins. Information pro-
16 vided shall include eligibility criteria, a description of
17 the location of trial sites, and a point of contact for
18 those wanting to enroll in the trial, and shall be in
19 a form that can be readily understood by members
20 of the public. Such information must be forwarded
21 to the Data Bank by the sponsor of the trial not
22 later than 21 days after approval by the Food and
23 Drug Administration.

1 “(B) Information pertaining to experimental
2 treatments for serious or life-threatening diseases
3 and conditions that may be available—

4 “(i) under a treatment investigational new
5 drug application that has been submitted to the
6 Food and Drug Administration pursuant to
7 part 312 of title 21, Code of Federal Regula-
8 tions;

9 “(ii) as a Group C cancer drug; or

10 “(iii) under an exemption for devices for
11 investigational use pursuant to part 812 of title
12 21, Code of Federal Regulations.

13 The Data Bank shall also include information per-
14 taining to the results of clinical trials of such treat-
15 ments, including information concerning potential
16 toxicities or adverse effects associated with the use
17 or administration of such experimental treatment.

18 “(4) For the purpose of carrying out this subsection
19 there are authorized to be appropriated such sums as may
20 be necessary.”.

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